REMARKS

Alleged Rejection Under 35 U.S.C. § 103(a)

Claims 12-16, 24, 25, 31-35, 37-40, 46, 47, 50, 51 and 62-67 are pending in the application and have been rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Conrad (U.S. Patent No. 6,054,299) in view of Moon et al. (The Journal of Biological Chemistry, vol. 275, No. 7, pages 4647-4653, 2/18/2000). Applicants have carefully reviewed the statement of the instant rejection as well as the cited documents and respectfully traverse because no *prima facie* case of obviousness is present.

The Office Action alleges that the '299 Patent reports large circular single stranded nucleic acid molecules that comprise antisense regions. The molecule referred to by the Office Action, pANTI, in Figure 1 of the '299 Patent is a cloning vector that is transformed or transduced into the appropriate host. '299 Patent at col. 2, ll.1-5, col. 4, ll.18-28. The cloning vector is a prokaryotic or eukaryotic plasmid vector. *Id.* at col. 3, ll. 4-5. The vector is used to produce DNA that forms stem-loop structures as shown in Figure 4 of the '299 Patent. Consequently, neither one of these molecules is a large circular single-stranded nucleic acid molecule comprising at least one target gene-specific antisense region that is *effective for reducing expression of a target gene*. Rather, pANTI is a *double stranded* plasmid cloning vector. The vector is not designed for effective reduction of expression of a target gene. Furthermore, the product of the cloning vector is not a large circular single-stranded nucleic acid molecule. As seen in Figure 4, the molecule is not circular. Instead, the molecule is a single stranded DNA whose structure merely favors formation into a stem loop molecule. The'299 Patent therefore teaches away from the use of a large circular single-stranded nucleic acid molecule comprising at least one target gene-specific antisense region that is effective for reducing expression of a target gene.

As a result, the combination of the '299 Patent and the Moon document do not render the present invention obvious. One of skill in the art would not have looked to the '299 Patent to use a large molecule as an inhibitor of gene expression because the double-stranded vector in the '299 Patent is used to produce single stranded DNA molecules that favor formation into a stem

loop structure. Thus the use of the vectors in the '299 Patent is one step removed from the use of the molecules in the present invention.

Moreover, one of skill in the art would not have a reasonable expectation of success in combining the documents. The combination of the '299 Patent with the Moon document would have led to the use of a double-stranded molecule which can be made single stranded either *in vivo* (or alternatively *in vitro*), which is not the present invention. Put another way, because the '299 Patent makes clear that the cloning vector produces stem-loop molecules that act in vivo or in vitro, there is no purpose in combining the molecules of the '299 Patent with a transfection effective carrier comprising a lipid to arrive at the present invention. The alleged combination would render the disclosure of '299 Patent unsatisfactory for its intended purpose.

In light of the foregoing, the instant rejection is misplaced for multiple reasons and so no *prima facie* case of obviousness is present. Applicants respectfully request that this rejection be withdrawn.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR §§1.16 and 1.17 that are not covered, in whole or in part, by a credit card payment enclosed herewith and to credit any overpayment to said Deposit Account No. 502486.

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Respectfully submitted,

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